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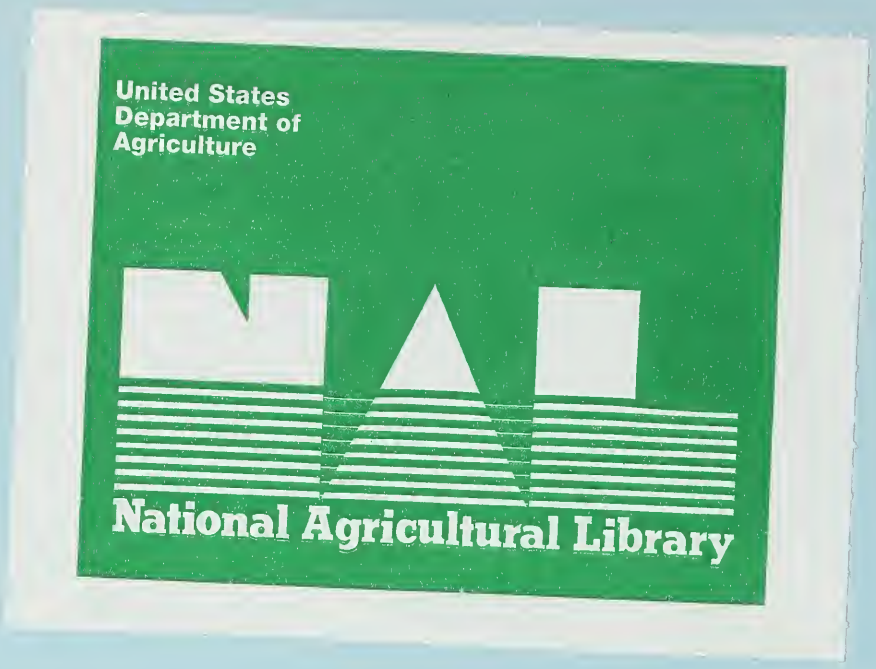
Generic HACCP Model for Heat Treated, Shelf Stable Meat and Poultry Products



Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

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United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

TO THE USERS OF THESE VOLUMES

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PR/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem.

As is consistently reiterated in the generic models themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. They also are not designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not designed to extend or further interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training

course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to discover typical food safety hazards that are reasonably likely to occur, as explicitly defined in 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is updating the generic models to include new technical information and to revise those parts that are out of date.

We hope that these documents are helpful.

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GENERIC HACCP MODEL

FOR

HEAT TREATED, SHELF STABLE MEAT AND POULTRY PRODUCTS

Introduction

The Hazard Analysis Critical Control Point (HACCP) system is a scientific approach to process control. It is designed to prevent the occurrence of problems by assuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards include biological, chemical, or physical contamination of food products. There are two basic kinds of bacteriological hazards: (1) infectious bacteria (e.g. *Escherichia coli* O157:H7 , *Listeria monocytogenes*, and *Salmonella*) that must be inactivated by an effective lethal treatment and prevented from contaminating the treated product, and (2) toxigenic bacteria (e.g. *Clostridium botulinum* and enterotoxigenic staphylococci) that must be inhibited from growing and producing their toxin during processing and in the finished product.

The Food Safety and Inspection Service (FSIS) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. As part of its efforts to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation would be made available for use on a voluntary basis by inspected establishments.

The generic models have been revised since their initial publication and distribution as DRAFTS. The most important change in the revised versions is to make certain that these models are fully consistent with the features of the final regulation. Also, other technical and editorial improvements have been made.

Throughout this generic model, FSIS discusses a HACCP team with members from different departments. In many very small establishments, there will not be separate departments with different employees. But, there will be employees who perform these different functions – often several of them. For purposes of explaining concepts, it is easier to speak as if these were different people, even though in many cases, they may be the same person carrying out more than one responsibility.

Each generic model can be used as a starting point for the development of plant-specific plan(s) reflecting actual plant environments and the processes conducted. The generic model is not intended to be used "as is" for plant specific HACCP plans.

The generic models are designed for use in conjunction with the list of process categories found in the HACCP regulations in section 417.2(b)(1).

> *(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:*
>
> *(i) Slaughter--all species.*
>
> *(ii) Raw product--ground.*
>
> *(iii) Raw product--not ground.*
>
> *(iv) Thermally processed--commercially sterile.*
>
> *(v) Not heat treated--shelf stable.*
>
> *(vi) Heat treated--shelf stable.*
>
> *(vii) Fully cooked--not shelf stable.*
>
> *(viii) Heat treated but not fully cooked--not shelf stable.*
>
> *(ix) Product with secondary inhibitors--not shelf stable.*

This generic model is designed for use with the process category: Heat treated--shelf stable.

The purpose of the process category listing in 417.2 is to set out the circumstances under which a HACCP team may develop a single HACCP plan for multiple products. This may be done when products are in the same process category, and food safety hazards, critical control points, and other features are essentially the same. There is a generic model for each process category, plus two for subcategories which present special issues: irradiated products and mechanically separated products.

In order to select the model or models that will be most useful for the activities performed in any specific plant, the following steps should be taken:

1) For slaughtering operations, select the model for the appropriate species.

2) For processed products, make a list of all products produced in the plant.

3) Examine the list and group like products, considering common processing steps and equipment used.

4) Compare the grouped products with the list of processes in the regulations; this step should reveal how many and which of the generic models might be useful.

Deciding on a generic model and which products can be covered by a single plan is an important achievement. If the team does it well, it can save a lot of unnecessary effort and paperwork.

Selecting an inappropriate generic model reduces its potential benefits. However, often the HACCP team will discover they have made this error when they develop their process flow diagram or during their hazard analysis. These are early stages in the process when it is relatively easy to make changes.

In any case, establishments must meet all regulatory requirements for their products.

Using This Generic Model

This generic model is designed to be used by establishments that produce heat treated, shelf stable product(s), the sixth process category listed above. The model can be used for all heat treated, shelf stable products: either meat or poultry. The generic model is not suitable for products that fall into any of the other process categories.

The model will be most useful to a HACCP team that includes access to one trained individual, as specified in 417.7(b).

> *(b)The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.*

It would be beneficial for other team members to have reviewed any of the various guidance materials available on how to develop a HACCP plan for your company, including several useful videos, handbooks, or computer programs. Once the HACCP team has prepared itself as thoroughly as possible in general HACCP principles and how to use them, this model should be helpful.

Note: This generic model includes a number of forms that can be used to record various types of required information. The forms themselves are examples; a company HACCP team can develop whatever forms it finds most useful. All the forms mentioned in this document are included in Appendix B; they appear in the order in which they are discussed in the text. Three of the forms in the previous generic model have been modified or replaced. The Form Letter Compliance with Purchase Specifications replaces the Form Letter Confirming *Salmonella*

Compliance with Performance Standards to reflect the change in the HACCP plan. The Room Temperature/Humidity Log is a revision of the Room Temperature Log. The column for temperature now includes both wet and dry bulb temperatures. The inclusion of both wet and dry bulb temperatures stresses the importance of humidity during the heating step. The Water Activity (a_w) Log replaces the Shrink Log as water activity is a better measure of proper drying for shelf-stability or safety.

All FSIS generic models are designed to assist establishments in applying the seven HACCP principles to their meat and poultry processing operations **AND** to meet the regulatory requirements of Part 417. Therefore, the definitions used in this and all other FSIS generic models are those found in 417.1:

> ***§ 417.1 Definitions.***
>
> *For purposes of this part, the following shall apply:*
>
> *Corrective action. Procedures to be followed when a deviation occurs.*
>
> *Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*
>
> *Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*
>
> *Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.*
>
> *HACCP System. The HACCP plan in operation, including the HACCP plan itself.*
>
> *Hazard. SEE Food Safety Hazard.*
>
> *Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.*
>
> *Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.*
>
> *Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.*

Process Flow Diagram and Product Description

To begin using this model, the company's HACCP team should first describe the product(s) which are part of this process category and covered by this HACCP plan. The product(s) should be described in two ways:

(1) by a simple diagram which shows the steps the company uses when it produces the product, and
(2) in a brief written description which provides key facts about the product and its use.

In this generic model, there are two examples for heat treated, shelf stable products – snack sticks and jerky. FSIS has developed certain forms as part of the examples in the generic models; **company HACCP teams are not required to use these forms.**

Figure 1 is an example of a **PROCESS FLOW DIAGRAM** for the production snack sticks and jerky in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the snack sticks and jerky produced in generic establishment X.

Once the company HACCP team in your establishment has prepared your Process Flow Diagram, they should verify it by walking through the establishment following the flow of product and making sure that all the steps of the process are included in the flow diagram. The team should also review the information provided on the Product Description to make sure all the key facts are included, such as identifying consumers, especially those with particular health problems or known to be at risk.

Note: If your process includes steps not included in this example, those steps should be added. Also, if your process does not include all the steps identified in this example, those steps would be omitted when conducting the hazard analysis. That is generally, how you use these generic model examples--just omit the features which do not apply to your operation or add those features of your operation not included in this example.

By completing a Process Flow Diagram and a Product Description, you have met the requirements of 417.2(a)(2). You can use the Process Flow Diagram in particular to help you complete the rest of the hazard analysis. Use the flow diagram to systematically review each step in the process and ask the question, "Is there a food safety hazard which is reasonably likely to occur which may be introduced at this step?" In answering the question, your HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once your product(s) are accurately described through the flow diagram and product description, the HACCP team should begin work on the **HAZARD ANALYSIS**. The hazard analysis is fundamental to developing a good HACCP plan and one that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

§ 417.2 Hazard Analysis and HACCP Plan.

> *(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.*
>
> *(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.*

Generic establishment X, which we are using for our example, is capturing these regulatory requirements on a 6-column **Hazard Analysis Form (See Figure 3)**. A good way to use a form like this is to create the first column by using the Process Flow Diagram and the second by answering the question. Once the HACCP team has considered all the steps in the flow diagram and determined if a food safety hazard could be introduced, it needs to consider whether the hazard is "reasonably likely to occur", using the meaning of this phrase included in 417.2(a). On the 6-column form used by generic establishment X, the third and fourth columns address this issue. If the establishment's HACCP team has decided that the hazard is not reasonably likely to occur, they enter "No" in column three, explain the basis for their determination in column four, and do not need to further consider activity at this point in the process.

If, however, the team has determined there is a "food safety hazard reasonably likely to occur" introduced at a certain point in the process, column five is used to describe a measure which could be applied to "prevent, eliminate, or reduce to acceptable levels" the food safety hazard identified in column three. Column six is used when a critical control point (CCP) is identified based upon the decision made in the hazard analysis. Each CCP has a number – the order corresponds to steps in the process. For example, 1 is the first CCP in the process flow, 2 the next, etc. The letter indicates whether the hazard is biological – B; chemical – C; or physical – P.

Look at the entries for "Drying" on the six column Hazard Analysis form for heat treated, shelf stable: the HACCP team has determined that *Staphylococcus aureus* may be present, so it has put a "Yes" in the third column. Column four explains the basis for the team's determination. In the fifth column, the HACCP team has described the preventive measures it will use to make sure that each hazard has been prevented, eliminated, or reduced to an acceptable level. For this hazard, the HACCP team decided that the water activity (a_w) will be checked to ensure that growth and toxigenesis will not occur. FSIS does not consider safe handling labels alone to be an adequate CCP for any pathogenic microorganisms such as bacteria and viruses.

IMPORTANT: **Manufacturers should not use the moisture protein ratio (MPR) as a measure of proper drying for shelf-stability or safety. This is because MPR is merely a product standard and because the water activity can vary greatly at any given MPR (as a result of the different kinds and quantity of solutes such as sugar and salt). It is product water activity that is best correlated to inhibition of each pathogen's growth.**

Note: Look at the entries for "Storage – (Cold – Frozen/Refrigerated) – Raw Meat/Poultry" on the six-column Hazard Analysis form: the HACCP team has determined that there is a food safety hazard reasonably likely to occur at this step in the process. Column four contains the reason for their thinking: pathogenic organisms can grow in this product if it is not kept sufficiently cool. Column five contains their description of a measure that will prevent the growth of these organisms: temperatures that are sufficiently low to preclude or inhibit growth.

You will notice that on our generic hazard analysis for snack sticks and jerky, there are seven food safety hazards likely to occur. The HACCP team has identified a point in the process to control each hazard.

When your HACCP team has completed their hazard analysis (whether they use this format or not), it is a good idea to review the flow diagram, the product description and the hazard analysis itself to make sure they are complete. Part 417.2(a)(3) includes a list of sources from which food safety hazards might be expected to arise. Reviewing that list could help the HACCP team check for completeness.

Note: If you are using this generic model to produce a different heat treated, shelf stable product or if you use a different process flow, you may have different hazards which are reasonably likely to occur. For these different hazards, there may be different measures which could be used for control purposes.

This, and all other FSIS generic models, contains a list of references which can help your HACCP team in making sure the hazard analysis is complete. These references are found in Appendix A. A member of your HACCP team might want to review at least some of the references to make sure hazards have not been omitted from the hazard analysis.

Completing the hazard analysis is a very significant and important element in developing your HACCP system. Your HACCP team should feel a real sense of accomplishment when they get this far; this is like completing the foundation of a house.

Developing Your HACCP Plan

The company HACCP team can now take the materials it developed while doing the hazard analysis and use them to build the **HACCP Plan.** Remember that one of the important objectives of the FSIS generic models is to provide examples which illustrate **how to meet the regulatory requirements of Part 417**, as well as to correctly apply the principles of HACCP. Part 417.2 (c) and (d) are the regulatory requirements:

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

Generic establishment X has prepared its HACCP plan for snack sticks and jerky on a six column form (**See Figure 4**). You do not need to use this form, although some kind of a form is probably the easiest way to present your HACCP plan.

Identifying CCPs

The first column on the HACCP Plan is used to enter information previously developed and contained on the Hazard Analysis Form. Part 417.2(c)(1) and (2) require that the food safety hazards identified in the hazard analysis be listed on the HACCP plan and that there be a CCP for each identified hazard. You will notice that there were seven points on the Hazard Analysis form for snack sticks and jerky where food safety hazards reasonably likely to occur were identified: 1) *Salmonella, L. monocytogenes, E. coli* O157:H7, *and Trichinella spiralis* on raw meat/poultry at receiving,; 2) growth of the same pathogens at cold storage,; 3) metal contamination during mechanical processing, 4) *S. aureus* proliferation at fermentation (snack sticks); 5) pathogen (including *L. monocytogenes)* survival and subsequent growth if inadequate heat and humidity is not used, 6) *S. aureus* proliferation at drying, and 7) post-lethality contamination at packaging by *Listeria monocytogenes*. The establishment HACCP team has chosen to have six CCPs to address these seven hazards: 1) purchase specifications, 2) proper cold storage of raw meat/poultry, 3) metal detectors prior to packaging and labeling, 4) correct pH is reached after the fermentation process is done, 5) proper time/temperature/humidity is reached during heat treatment, and 6) proper water activity (a_w) is reached after drying is completed.

Look at the entries for "Heating Treatment (jerky)" six column HACCP plan form for heat treated, shelf stable; the HACCP team determined that humidity must be applied to during heating in order to eliminate the pathogens of concern (e.g., *Salmonella*, *E. coli* O157:H7). Bacterial resistance to heat has been shown to increase with a decrease in the moisture level. If humidity is not applied during heating, the bacteria may survive the heat process and remain infectious or grow and produce toxin.

After identifying its CCPs, the HACCP team proceeded to consider critical limits, monitoring procedures and their frequencies, and verification procedures and their frequencies, and HACCP records.

In deciding what would be the critical limits, the HACCP team first considered whether there were any regulatory requirements which had to be met and would function as critical limits.

They did find FSIS regulatory requirements and guidelines for drying, so they set the critical limit(s) using criteria as specified by FSIS for the control of pathogens.

Once they had decided on their critical limits, they needed to identify how the monitoring procedures would be carried out and at what frequency.

For their drying step, the establishment had a production employee perform water activity (a_w) checks on each lot and the drying time/temperature will be monitored using room recorder charts.

These decisions by the HACCP team regarding critical limits, plus monitoring procedures and their frequencies, are written up in columns two and three of the HACCP Plan.

The team then went on to consider appropriate verification procedures; the team knew that there were different types of verification and that Part 417.4(a)(2) included specific regulatory requirements for each. The regulatory requirements for ongoing verification are:

> *(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:*
>
> *(i) The calibration of process-monitoring instruments;*
>
> *(ii) Direct observations of monitoring activities and corrective actions; and*
>
> *(iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.*

The HACCP team decided they could verify through the following procedures and frequency:

1. QA supervisor will review the temperature, metal detector, and fermentation records daily and water activity and smokehouse/product temperature logs once per shift.
2. Maintenance supervisor will verify the accuracy of the room temperature/humidity log, functioning of the metal detector, product temperature recording chart, and drying room recorder once per shift.
3. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 1°F accuracy as necessary.
4. The QA supervisor will observe the QA technician perform each monitoring activity once per shift.

The HACCP team described the verification procedures and their frequencies in the fifth column of their HACCP plan.

The HACCP team for generic establishment X knew that their HACCP Plan needed to provide for a recordkeeping system. They wanted their records to be easy to create and understand.

They wanted to be sure their records met regulatory requirements, so they reviewed part 417.5(a) and (b):

> ***§ 417.5 Records.***
>
> *(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:*
>
> *(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;*
>
> *(2) The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*
>
> *(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*
>
> *(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

The HACCP team decided that their records would be kept on some simple forms, some of which the team itself devised. On its HACCP Plan, generic establishment X has listed the names of the forms it will be using for monitoring and verification records. They are: Form Letter Confirming *Salmonella* Compliance, Receiving Log, Thermometer Calibration Log, Room Temperature/Humidity Log, Metal Detection Log , Smokehouse/Product Temperature Log, Fermentation Log, Water Activity Log, and Corrective Actions Log.

Column four (HACCP Records) in the HACCP Plan references the Corrective Actions Log. This is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. Column six in the HACCP Plan references the planned corrective actions for each CCP. The HACCP team carefully reviewed the regulatory requirements for planned corrective actions found at 417.3(a):

> ***§ 417.3 Corrective actions.***

> *(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:*
>
> *(1) The cause of the deviation is identified and eliminated;*
>
> *(2) The CCP will be under control after the corrective action is taken;*
>
> *(3) Measures to prevent recurrence are established; and*
>
> *(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

The HACCP team has developed a specific corrective action plan which will be followed whenever there is a deviation from a critical limit at a CCP; each of the planned corrective actions meets the four regulatory requirements of 417.3(a). Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Action Log to create a record of their actions. The Corrective Action Log forms are available at CCPs, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Action Logs, which have been used during the day, are turned in to the HACCP coordinator.

There is one final verification/recordkeeping requirement which the company must perform; it is found at 417.5(c):

> *(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.*

In generic establishment X, product is shipped out, often in small lots, throughout the day. This means that pre-shipment verification checks must be as complete as possible when finished product is in storage, so that a shipment can be made up quickly and moved into distribution channels.

The establishment uses a half day lotting system and a midshift cleanup. While the midshift cleanup is being performed, QA personnel or the HACCP coordinator review results of monitoring and verification checks applied to that lot; if there were deviations from critical limits, they review the Corrective Action Logs to make sure all appropriate planned responses were carried out. If everything is in order and there are complete records showing that the establishment has controlled production of this product through its HACCP system, the HACCP

coordinator will sign the pre-shipment review form which the HACCP team devised for this purpose.

Note: It is not a regulatory requirement that a separate form be used for pre-shipment review; in addition, FSIS has indicated that it will be very flexible in accepting a variety of arrangements for accomplishing pre-shipment review to reflect the variety of commercial practices which it has encountered in the industry. It is, however, important to remember that pre-shipment review is a regulatory requirement that must be met, as it indicates that the establishment is taking full responsibility for the product having been produced under a well-functioning HACCP system.

The HACCP team believes it has now completed preparation of the documents which are necessary to meet regulatory requirements for a Hazard Analysis and a HACCP Plan for their heat treated, shelf stable production process. They have secured a copy of FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Requirements, the HACCP Basic Compliance Checklist which will be used by inspection program personnel. The HACCP team has modified the inspection form to make the statements into positives, and now has a checklist for its own use to make sure they have not omitted anything in their plan development and preparation. When they are confident that they have done what is necessary, they will turn their Hazard Analysis and HACCP Plan over to the establishment owner for decisions about implementation.

APPENDIX A

References for General HACCP and Regulatory Issues

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   Useful sections in particular are:
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   Chapter 4 – chemical hazards, pp. 27-32
   Chapter 5 – physical hazards, pp. 33-35
   Appendix A – NACMCF HACCP
   Appendix C – Model HACCP plans

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    Chapter 10 – raw meat and poultry, pp. 176-193
    Chapter 11 – roast beef, pp. 234-238
    Chapter 11 – canned ham, pp. 238-242

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    Chapter 9 – raw meat, pp. 193-199
    Chapter 9 – processed meats, pp. 199-216

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    Useful sections in particular are:
    Chapter 4 – meat and poultry slaughter, pp. 58-71
    Chapter 5 – processed meats, pp. 72-107
    Chapter 7 – risk analysis, pp. 134-154
    Chapter 13 – predictive modeling, pp. 330-354

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    Useful sections in particular are:
    Chapter 11 – forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken

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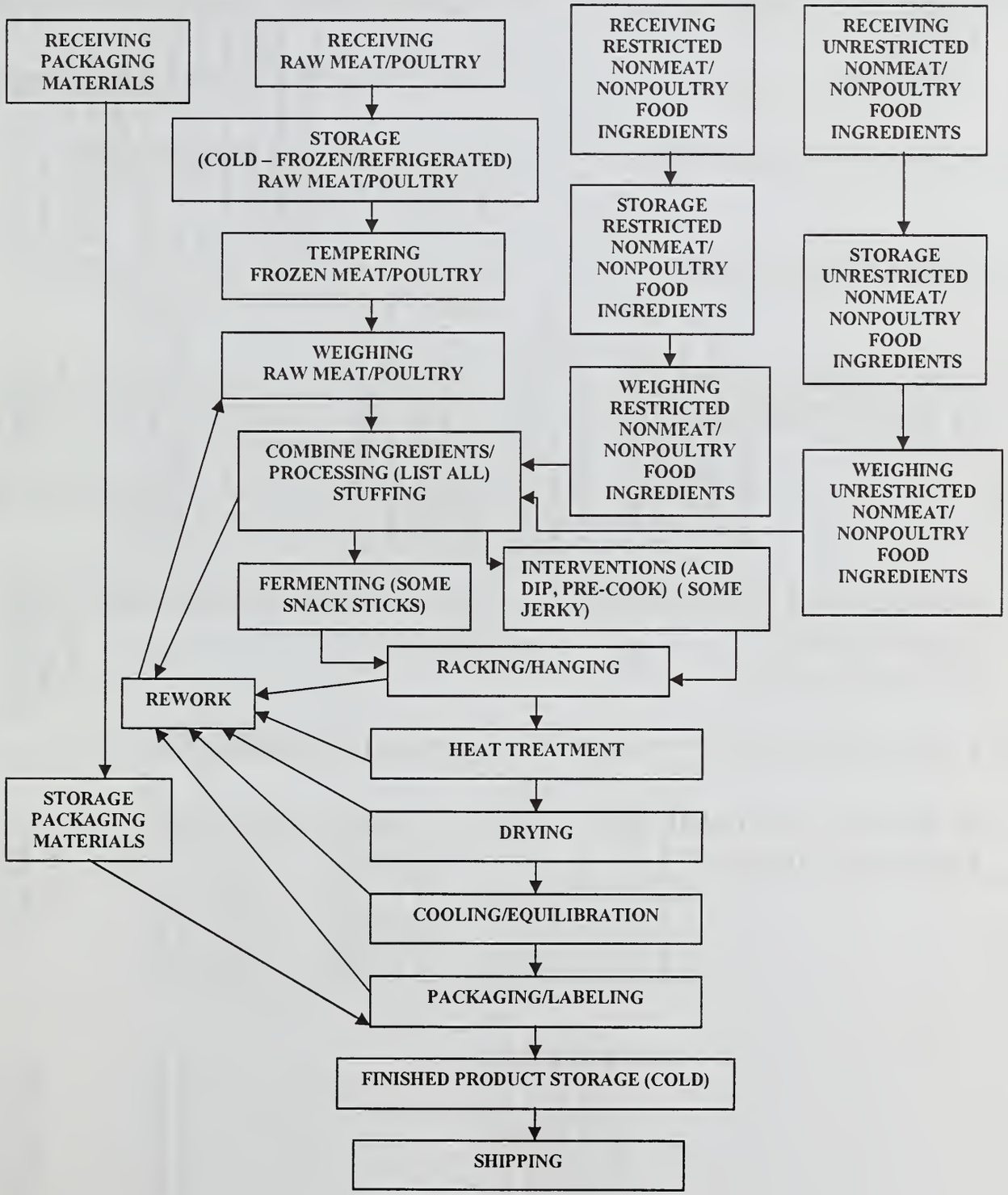
APPENDIX B

PROCESS FLOW DIAGRAM

Figure 1

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT: SNACK STICKS, JERKY



PRODUCT DESCRIPTION

Figure 2

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE	
PRODUCT: SNACK STICKS, JERKY	
1. COMMON NAME? TYPES: COMMON NAME?	SNACK STICKS (SOME FERMENTED BEEF JERKY (NON-FERMENTED)
2. HOW IS IT TO BE USED?	CONSUMED AS PURCHASED (READY TO EAT)
3. TYPE OF PACKAGE?	BULK-PACKED (E.G., PLASTIC BAG, VACUUM PACKED)
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	VARIES WITH PACKAGING AND STORAGE TEMPERATURE: MAY LAST 6 MONTHS NON-REFRIGERATED & INDEFINITELY UNDER REFRIGERATION
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	WHOLESALE TO DISTRIBUTORS ONLY
6. LABELING INSTRUCTIONS?	KEEP REFRIGERATED
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	KEEP REFRIGERATED

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving – Raw Meat/Poultry	**Biological: Pathogens** *Salmonella* *Listeria monocytogenes* *E. coli* O157:H7 *Trichinella spiralis*	**Yes**	**Pathogens may be present on incoming raw product.**	Suppliers must meet purchase specifications to ensure the raw product does not contain excessive levels of pathogens that cannot **be controlled through subsequent heat treatment & drying.**	**1B**
	Chemical – None				
	Physical – Foreign materials such as broken needles	**No**	**Plant records show that there has been no incidence of foreign materials in products received into the plant.**		
Receiving – Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients; Packaging Materials	**Biological – None**				
	Chemical – Packaging material not acceptable for intended use.	**No**	**Letters of guaranty are received from all suppliers of packaging materials.**		
	Physical – Foreign materials (metal, glass, wood, etc.)	**No**	**Plant records demonstrate that foreign material contamination has not occurred during the past several years.**		

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Storage – Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients; Packaging Materials	Biological – None				
	Chemical – None				
	Physical – None				
Storage (Cold – Frozen/Refrigerated) – Raw Meat/Poultry	Biological – Pathogens *Salmonella* *Listeria monocytogenes* *E. coli O157:H7* *Trichinella spiralis*	Yes	*Salmonella, E. coli O157:H7,* and *Listeria monocytogenes* are reasonably likely to grow in this product if temperature is not maintained to preclude or inhibit their growth.	Maintain product temperature at or below a level sufficient to preclude or inhibit pathogen growth. Pathogens can be controlled through subsequent heat treatment & drying.	2B
	Chemical – None				
	Physical – None				
Tempering Frozen Meat/Poultry	Biological – None				
	Chemical – None				
	Physical – None				
Weighing Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients	Biological – None				
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Weighing Raw Meat/Poultry	Biological – None				
	Chemical – None				
	Physical – None				
Combine Ingredients/ Processing (Includes one or more of the following: grinding, chopping, mixing, stuffing, forming, and slicing)	Biological – None				
	Chemical – None				
	Physical – Metal Contamination	Yes	Plant records show that during mechanical processing metal contamination has occurred.	Metal detectors are used prior to packaging.	3P
Rework	Biological –None				
	Chemical – None				
	Physical – None				
Marinating	Biological –None				
	Chemical – None				
	Physical – None				
Racking/Hanging	Biological – None				
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Fermenting (Used for pH reduction on some snack sticks)	Biological – Pathogens *Staphylococcus aureus*	Yes	Potential growth *S. aureus* with the failure of the fermentation process. Growth & toxigenesis can occur.	pH should be reached during fermentation according to the required degree hours needed to inhibit *S. aureus*.	4B
	Chemical – None				
	Physical – None				
Heat Treatment	Biological – Pathogens (*Listeria monocytogenes, Salmonella, Staphylococcus aureus, E. coli O157:H7, T. spiralis*)	Yes	Potential survival and growth of pathogens and toxigenesis from *S.aureus* with the failure of adequate heat and humidity.	Heat treatment using appropriate time/temperature/humidity to produce lethality/pasteurization.	5B
	Chemical – None				
	Physical – None				
Drying	Biological – Pathogens *Staphylococcus aureus*	Yes	Growth of pathogens with the failure of the drying process. *L. monocytogenes* can grow if drying inadequate and *S. aureus* growth & toxigenesis can occur.	Low water activity (a_w) precludes bacterial pathogen growth. The a_w required for *S. aureus* (0.86) is lower than that for other pathogens.	6B
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Cooling/Equilibration	Biological – None				
	Chemical – None				
	Physical – None				
Packaging/Labeling	Biological – Pathogens *Listeria monocytogenes*	Yes	Potential post-lethality exposure to *L. monocytogenes*.	*L. monocytogenes* growth precluded by drying - water activity of product much less than 0.92 min required for Lm growth.	
	Chemical – None				
	Physical – None				
Finished Product Storage (Cold)	Biological – None				
	Chemical – None				
	Physical – None				
Shipping	Biological – None				
	Chemical – None				
	Physical – None				

Figure 3

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
1B Receiving – Raw Meat/Poultry	Supplier documents that purchase specifications have been met.	Receiving personnel will check each shipment for required documentation.	Form Letter Confirming Purchase Specifications as met. Receiving Log Corrective Action Log	Every two months QA will request *Salmonella* data results from companies for at least 2 suppliers.	Will not receive product that is not documented as meeting purchase specifications.. Product will be held or returned until documentation is provided. If supplier shows failure to meet purchase specifications on 2 consecutive deliveries, the supplier will be delisted until results show the purchase specifications have been met.
2B Storage (Cold– Frozen/ Refrigerated – Raw Meat/Poultry	Raw product storage areas will not exceed 40° F in refrigerated rooms or exceed 30° F in freezer rooms.	Maintenance personnel will check raw product storage areas temperature every two hours to determine that temperature requirement is met.	Room Temperature/ Humidity Log Thermometer Calibration Log Corrective Action Log	Maintenance supervisor will verify accuracy of the Room Temperature Log once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 1° F accuracy as necessary. QA supervisor will review temperature records daily. Once per shift QA supervisor will observe the QA technician perform the monitoring activity.	QA will reject or hold product dependent on evaluation of time/temperature deviation. Product will then either be condemned or processed depending on the evaluation of the deviation. Maintenance will conduct repairs & make adjustments to controls as necessary. QA will identify the cause of the deviation and prevent reoccurrence. Product storage method will be assessed.

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3P Mechanical Processes	No metal particles to exceed 1/32 inches. Any kick out product will be visually examined & reworked.	The kick out device will be monitored by QA every 3 hours & No. of rejects recorded.	Metal Detector Performance Log Corrective Action Log	Maintenance supervisor will verify metal detector is functioning & adjust/maintain as per manufacturer's specifications. QA will verify that the metal detectors are functioning as intended by running a seeded sample through the metal detectors twice per shift (once in the AM and once in the PM) and record results in the metal detector log. QA supervisor will review metal detector records daily. Once per shift QA supervisor will observe the QA technician perform the monitoring activity.	Mechanical separation line supervisor will control and segregate affected product. Maintenance personnel will identify and eliminate the source of the contamination or repair the metal detector if product was determined not to contain metal contamination. Preventive maintenance program will be revised as required. QA will run seeded sample through metal detector after repair. All potentially contaminated product will be examines by X-ray or visual examination back to last acceptable check.

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
4B Fermenting (Some Snack Sticks)	pH … 5.3 just prior to heat treatment.	QA technician will test pH of 10 pieces of each lot by probe within 3 hours & prior to heat treatment.	Fermentation Log Corrective Action Log	QA Supervisor will verify accuracy of the Fermentation Log once per shift. QA will check all pH meters used for monitoring and verification for accuracy daily and calibrate for accuracy as necessary using acidic & basic standard solutions. QA supervisor will review fermentation records daily. QA supervisor will observe QA technician perform monitoring activity once per shift.	QA will segregate and hold all affected product until correct pH is achieved or product will be reworked as per Process Authority recommendations or condemned depending on fermentation pH. Fermentation time/temperature specifications and product formulation will be reassessed & revised if necessary. QA will identify the cause of the deviation and prevent reoccurrence.

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
5B Heat Treatment (snack sticks)	Snack sticks to be cooked to internal temp. 145°F.	Final temperature taken by internal probe and check 10 sticks in coldest part of smokehouse for each lot before removal from smokehouse & at completion of cook cycle.	Smokehouse/ Product Temperature Log Thermometer Calibration Log Corrective Action Log	Once per shift the QA supervisor will review the Smokehouse/ Product Temperature Log. Maintenance supervisor will verify accuracy of the product (internal) temperature recording charts once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 1°F accuracy as necessary. QA supervisor will review temperature records daily. Once per shift QA supervisor will observe the QA technician perform the monitoring activity.	QA will reject or hold product dependent on time and temperature deviation. For heating deviations the Process Authority determines product disposition. QA will identify the cause of the deviation and prevent reoccurrence.
5B Heat Treatment (jerky)	Jerky to be cooked to internal temp. 160°F with 90% humidity throughout the cook.*	Final temperature taken by internal probe in coldest part of oven for each lot before removal from oven & at completion of cook cycle. Temperature monitored by wet bulb thermometer.	RoomTemperature / Humidity Log Thermometer Calibration Log Corrective Action Log	Once per shift the QA supervisor will review the Smokehouse/ Room Temperature/Humidity Log. Maintenance supervisor will verify accuracy of the product (internal) temperature recording charts once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 1°F accuracy as necessary. QA supervisor will review temperature records daily. Once per shift QA supervisor will observe the QA technician perform the monitoring activity.	QA will reject or hold product dependent on time and temperature deviation. The Process Authority modeling can be used to make a determination on product disposition. QA will identify the cause of the deviation and prevent reoccurrence.

* Humidity control is critical during the heat treatment. Without adequate humidity, the required level of pathogen reduction will not be achieved.

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
6B Drying	Reach established water activity (a_w) * Jerky (≤ 0.7 a_w for product in contact with air)	a_w checks will be done on 10 individual samples for each lot by production employee. Drying time/temperature will be monitored using room recorder charts.	Water activity (a_w) Log Drying Room Recorder Charts Thermometer Calibration Log Corrective Action Log	Maintenance supervisor will verify the accuracy of the drying room recorder once per shift. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 1° F accuracy weekly. Drying room recorders will be calibrated each week by QA to within 1° F accuracy. QA supervisor will review and a_w logs and drying room recording charts once per shift. Once per shift QA supervisor will observe the QA technician perform the monitoring activity.	If a deviation from a critical limit occurs, the following corrective actions will be taken: 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be monitored hourly after the corrective action is taken to ensure that it is under control. 3. When the cause of the deviation is identified, measures will be taken to prevent it from recurring e.g., if the cause is equipment failure, preventive maintenance program will be reviewed and revised, if necessary. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

Signature: _____ **Date:** _____

Figure 4

* Manufacturers should not use MPR as a measure of proper drying for shelf-stability or safety. This is because MPR is merely a product standard and because the water activity can vary greatly at any given MPR (as a result of the different solutes such as sugar and salt). It is product water activity that can be easily correlated to inhibition of each pathogen's growth.

Form Letter Confirming Compliance with Purchase Specifications

Date

To: Plant XYZ

This is to confirm results of purchase specification tests completed during the past six months from your establishment listed below.

Thank you.

Product	Lot ID	Date Received	Test Results	Purchase Specifications Met? (Yes or No) If not met, reason is indicated.

THERMOMETER CALIBRATION LOG

Calibrate to 32^0 F while thermometer is in slush ice water

Date	Time	Department or Area	Thermometer ID#	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments

- **If a thermometer is broken or taken out of service, document this in the comments column.**

Reviewed by: _____

Date: _____

GENERIC ESTABLISHMENT X: ROOM TEMPERATURE/HUMIDITY LOG

ROOM:_____ **DATE:**_____

TIME	TEMP		Deviation from CL? (Check if yes)	If Yes, Action?	Monitored by:	Verified by:
	WET BULB	DRY BULB				

GENERIC ESTABLISHMENT X: METAL DETECTION LOG							
Date	Product	Lot #	Results	Seeded Sample	Time	Monitored By	Verified By

SMOKEHOUSE/PRODUCT TEMPERATURE LOG*

CCP: _____

	Smokehouse/Product Temperature						
Smokehouse/ Product Temp: **Lot #**						**Operator's Initials/ Time/Date**	**Verified by: Initials/ Time/Date**
TIME:							

***Smokehouse/Product Temperature Log may be used if smokehouse chart is not available.**

Critical Limit:

Corrective Action(s):

FERMENTATION LOG

CCP: _____

Critical Limit:

Corrective Action(s):

Instructions: Record requested information. Time and temperature may be recorded on log or taken from chart recorded.

Date	Lot ID	Time In*	Time Out*	Temperature**	pH	Comments	Operator Initials/ Verification Date and Initials

*Smokehouse chart may be used for recording time-in/time-out * Attach smokehouse charts if available.

WATER ACTIVITY (a_w) LOG

Date/ Time	Lot ID	a_w	Comments	Monitored By	Verified By	Verification Date

CORRECTIVE ACTIONS LOG

Product: _____ **Lot #** _____

CCP	Deviation/ Problem	Corrective Action Procedures/Explain	Disposition of Product	Responsible Person	Date/Time

SIGNATURE: _____ **DATE:** _____

PRE-SHIPMENT REVIEW LOG

Date:_____

PRODUCT	LOT ID	TIME RECORDS REVIEWED	BY WHOM	LOT RELEASED FOR SHIPMENT? SIGNATURE	COMMENTS *

*Monitoring frequency as per plan; Critical limits met; Certification (if applicable) as per plan; Deviations if occurred were reviewed for appropriate corrective actions; Records complete and accurate.

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